

Centers for Disease Control and Prevention

Center for Global Health Extramural Research Program Office

Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation:
Amendment 2

RFA-GH-16-007

Application Due Date: 06/28/2016

Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation:

Amendment 2

RFA-GH-16-007

TABLE OF CONTENTS

[Part 1. Overview Information](#)

Key Dates

Required Application Instructions

Executive Summary

[Part 2. Full Text](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Center for Global Health Extramural Research Program Office (CGH ERPO)

Center for Global Health (CGH)

Funding Opportunity Announcement (FOA) Title

Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation: Amendment 2

Activity Code

U01

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-GH-16-007

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.326

Category of Funding Activity:

Health

FOA Purpose

The purpose of this funding opportunity is to strengthen country capacities and capabilities to prevent, detect, and effectively respond to current and emerging public health threats, including potential outbreaks and the spread of infectious diseases. This FOA supports research that will provide Ministries of Health and other key stakeholders with the data and evidence to support strategies for the development of public health protection systems, interventions, and policies. Research projects are limited to countries with either a CDC field office, or CDC presence established through deployment.

Key Dates

Publication Date:

To receive notification of any changes to RFA-GH-16-007, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 05/25/2016

Application Due Date: 06/28/2016

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: **08/03/2016**

Secondary Review: **08/31/2016**

Estimated Start Date: **09/30/2016**

Expiration Date: **06/28/2016**

Due Dates for E.O. 12372: Due no later than 60 days after the application receipt date.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

The Research Strategy component of the Research Plan is limited to a maximum of 25 pages per Project..

Executive Summary

Summary of Amendment 2

RFA-GH-16-007 Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation Amendment 2

1. Part 1– Required Application Instructions and Executive Summary

Clarified that Research Strategy is limited to 25 pages maximum per Project.

Deleted text relating to Year 1 budget and anticipated number of awards

2. Part 1– Overview Information

Section I. Funding Opportunity Description

1. Approach

Objectives/Outcomes

Deleted “proposals, proposal priorities”

Collaboration /Partnerships

Deleted “Applications will only be accepted from Ministries of Health (MoHs) or their bona fide agents...”

Revised second paragraph to remove “eligible applicants (MoHs) or their bona fide agents

3. Section II – Award Information

Deleted anticipated number of awards

4. Section III - Eligibility Information

5. Responsiveness – added clarification on how to label projects

5. Section IV. Application and Submission Information

2. Deleted “proposal” and replaced with “project”

3. Added language to Letter of Intent to clarify what the LOI should include

5-3. Research Strategy – clarified that limit is 25 pages per Project per Objective

6. Appendix – changed maximum number of PDF documents allowed to 25

7. Page Limitations – changed maximum number of appendices pages to 300.

6. Section V – Application Review Information

4. Review and Selection Process

Added language to clarify which projects will be externally peer reviewed or undergo an objective review

Added language to clarify how projects will be reviewed and scored

7. Section VIII – Other Information

Added Frequently Asked Questions

- **Purpose.** The purpose of this funding opportunity is to strengthen country capacities and capabilities to prevent, detect, and effectively respond to current and emerging public health threats, including potential outbreaks and the spread of infectious diseases. This FOA supports research that will provide Ministries of Health and other key stakeholders with the data and evidence to support strategies for the development of public health protection systems, interventions, and policies. Research projects are limited to countries with either a CDC field office, or CDC presence established through deployment.
- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** Awards issued under FOA are contingent upon availability of funds. Note that multiple Projects may be awarded to the same applicant.

The estimated total funds available for the entire project period has not been set.

The project period will run from September 30, 2016 – September 29, 2021.

- **Application Research Strategy Length:** 25 pages per Project per Objective.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed
- **Application Type.** New
- **Special Date(s).** Program should insert dates for any planned technical assistance conference calls or other special dates. **Preapplication Conference call: Wednesday, May 18, 2016, 8:00 a.m. EST. Toll Free: 1-866-692-3158 Participant code: 94344757**
- **Application Materials.** See [Section IV.1](#) for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Section 301 (a) of the Public Health Service Act (42 U.S.C. 241 (a)) and Section 307 of the Public Health Service Act (42 U.S.C. 242)

1. Background and Purpose

Global health protection advances public health interventions, policies, programs, and systems in response to current, emerging, and future public health threats. Findings provided by operational research or implementation science help establish the metrics and benchmarks for defining and measuring success.[\[i\]](#) The U. S. Government (USG) recognizes and supports necessary global health protection efforts that will improve and strengthen both global and national capacities to prevent, detect, and effectively respond to infectious disease and other current or emerging public health threats; in order to facilitate and maintain the vision of:

A world safe and secure from global health threats posed by infectious diseases —where it is possible to prevent or mitigate the impact of naturally-occurring outbreaks and intentional or accidental releases of dangerous pathogens, rapidly detect and transparently report outbreaks when they occur, and employ an interconnected global network that can respond effectively to limit the spread of infectious disease outbreaks in humans and animals, mitigate human suffering and the loss of human life, and reduce economic impact.[\[ii\]](#)

The need for public health protection and security is further justified in the article series titled, “Global health security: the wider lessons from the West African Ebola virus disease epidemic,” published in 2015 by the Lancet. The Global Health Security Agenda (GHSA), International Health Regulations (IHR), and additional US-led public health protection efforts call for the implementation of global health protection and the integration of programs with timely and relevant operational research.[\[iii\]](#)

This FOA directly supports operational research (implementation science) to develop an evidence base that supports the global implementation of public health protection efforts. Effective research projects are those that expand the evidence base that informs national priorities and implementation plans and result in models, strategies and implementations plans, such as validated field diagnostics and burden of disease assessments. Research funded through this FOA are expected to collect relevant data and evidence that supports effective and efficient strategies for strengthening the impact of CDC-supported global health protection initiatives.

[\[i\]](#) <http://www.wsj.com/articles/SB10001424127887323539804578261780648285770>

[\[ii\]](#) United States Government and Centers for Disease Control and Prevention Global Health Security Vision and Overarching target: http://www.cdc.gov/globalhealth/security/pdf/ghs_overarching_target.pdf

[\[iii\]](#) Annex 1, IHR (2005): State parties shall assess the ability of existing national structures and resources to meet the minimum core requirements and, as a result, develop and implement plans of action (http://apps.who.int/iris/bitstream/10665/181594/1/9789241549325_eng.pdf?ua=1&ua=1); GHSA Action Package (2014).

Healthy People 2020 and other National Strategic Priorities

Healthy People 2020 goals supported by this FOA include:

GH-4 - Increase the number of public health professionals trained by Global Disease Detection (GDD) programs worldwide.

GH-5 - Increase diagnostic testing capacity in host countries and regionally through the Global Disease Detection (GDD) Regional Centers.

Other national and international priorities include:

The Department of Health and Human Services’ (HHS) Global Health Strategy maintains three goals to support HHS’ global health vision of a healthier, safer world: 1) protect and promote the health and well-being of Americans through global health action; 2) provide leadership and technical expertise in science, policy, programs and practice to improve global health; and 3) advance United States interests in international diplomacy, development, and security through global health action.

IHR’s Article 44, supporting WHO International Health Regulation and Global Health Security Agenda

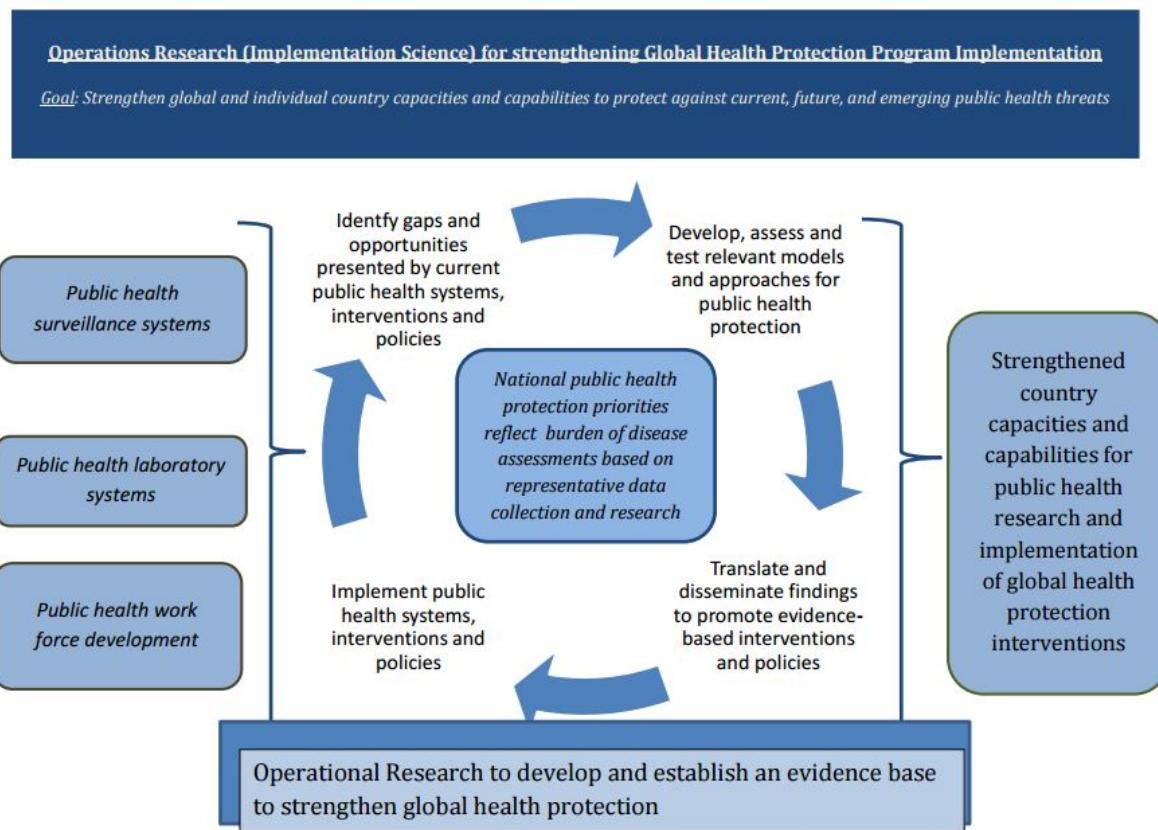
requirements.

The second Presidential Policy Directive (PPD): Implementation of the National Strategy for Countering Biological Threats.[\[i\]](#)

[i] <http://fas.org/irp/offdocs/ppd/>

Public Health Impact

Public Health Impact: Research provided through this FOA will inform and yield effective implementation of public health protection interventions and policies, represented in the following graphic:



Relevant Work

N/A

2. Approach

Research questions and projects applied for under this FOA should reflect the country's current and projected capacities and capabilities.

The operational research supported by this FOA will generate an evidence base that strengthens country capacities and capabilities to prevent, detect, and respond to global health threats such as infectious disease outbreaks and subsequent spread. Supported projects will help Ministries of Health and stakeholders prioritize and develop plans for combatting the pathogens associated with the most dangerous threats to national and regional health security. Comprehensive research will examine the overlap between communicable and non-communicable disease threats and identify shared surveillance and prevention approaches.

It is expected that research findings will facilitate the implementation of key activities such as field diagnostics, burden of disease assessments, and identification or development of relevant models and national implementation plans. Supported projects will strengthen the impact of global health protection programs and policies within one or more of the following objectives:

1. Operational research for national public health surveillance systems
2. Operational research for national public health laboratory systems
3. Operational research for national public health workforce development and retention
4. Develop and create an evidence base to establish national public health priorities

Applicants are encouraged to consider the following proposed objectives. In subsequent years, additional objectives may be considered. Applicants applying to multiple objectives must provide a written plan indicating assurance of coordinated management and administrative support.

Objectives/Outcomes

Objective 1. Operational research for national public health surveillance systems

Effective public health surveillance provides a cornerstone for a nation's public health protection efforts and requires development of a system sensitive enough to detect new outbreaks and research that will further efforts to establish baseline data and standards relating to host country's national public health surveillance capabilities and capacities. Comprehensive surveillance research projects are those that use indicators as a method for measuring the extent of achievement or success that meets this objective.

Year one applications addressing this objective should include a minimum of one, but not more than three, of the following projects:

1. Develop an evidence-based approach to improve current surveillance systems through strengthening civil registration and vital statistics as well as cause of death certification, risk factor surveillance, data analysis and collection.
2. Develop, determine, and conduct cost studies for replicable population, community, and facility-based surveillance models.
3. Identify and evaluate feasible approaches or implementation models for emergency infectious diseases surveillance systems that can be applied quickly and efficiently during an outbreak or other health emergency.
4. Investigate potential methodologies to extend the foundational capacities of Integrated Disease Surveillance and Response (IDSR) and other national surveillance capabilities.
5. Conduct operational research to identify ways to link national or local public health surveillance systems with internationally endorsed surveillance methods such as IDSR, population-based surveillance, syndromic surveillance, sentinel surveillance, events or other community-based surveillance initiatives and systems.
6. Identify and assess, through pilot programs or other evaluation methods, appropriate technology, approaches, and platforms to support surveillance in different settings (e.g. text messaging, secure methods for data storage and integration, surveillance-supported devices, power solutions, etc.).
7. Demonstrate effective analysis and utilization of secondary data and, where available, existing

- surveillance specimen repositories to augment country's surveillance and disease burden assessment capacity.
8. Demonstrate how national population based sero-surveys can be used to identify disease and vaccination priorities.
 9. Demonstrate how nationally and geographically representative facilities surveys can be used to measure primary health care quality and facility utilization and response preparedness over time.
 10. Identify feasible methods to conduct autopsies after unexplained deaths and evaluate the impact that such methods may have on current or future sentinel surveillance efforts or systems.
 11. Other: Proposed research that addresses a topic not listed above will only be considered if accompanied by a detailed project justification.

Objective 2. Operational research for national public health laboratory systems

National laboratory systems that possess the capacities and capabilities to prevent, detect, and respond to public health threats require on-going assessment and evaluation. This FOA supports research designs that will provide MOHs with the data necessary to improve the implementation or creation of public health laboratory systems. Comprehensive investigations or research efforts are those that engage the full laboratory system and its stakeholders including local to national level laboratories, clinical sentinel laboratories, and emergency operations centers.

Year one applications addressing this objective should include a minimum of one, but not more than three, of the following projects:

1. Validate new diagnostic tools including rapid diagnostic and multiple pathogen test platforms that address national disease and program delivery priorities.
2. Assess and determine an evidence-based, long-term, method for specimen transport that strengthens epidemiology capacities and utilizes resources from nations with demonstrated outbreak response to countries or regions that are more vulnerable to public health threats.
3. Determine and develop new laboratory system approaches that would significantly shorten the time intervals from symptom onset to diagnosis and treatment to reduce morbidity and mortality.
4. Establish an evidence-base for a feasible approach for building networked diagnostic capabilities at different levels of the laboratory system, both horizontal and vertical, below the national reference lab level.
5. Identify and test effectiveness of approaches to determine if/where to develop diagnostic-specific capacities in addition to the national reference lab level
6. Conduct operational research surrounding specimen transport to laboratories and examine how recent advancements in diagnostic capabilities could provide alternative methods for transporting medical supplies or test specimens to and from more remote areas.
7. Develop an evidence base that assesses the necessity, cost, and effectiveness of national laboratory systems and other approaches for conducting diagnostic tests.
8. Develop an evidence base that assesses approaches for an economically feasible and sustainable laboratory results reporting system to national labs and MOH.
9. Develop, determine, and assess the cost of potential models for national reference lab creation or alternatives for country-specific implementation.
10. Assess the feasibility and efficacy of conducting diagnostics and research with dried blood spot samples and tests either in addition to, or in lieu of, using plasma.
11. Identify potential approaches for using fixated blood for medical tests in order to identify requirements for effective implementation of new diagnostic methods within specified areas, countries, or regions.
12. Develop an evidence base that determines what if any, biological properties of a sample, such as fixated blood, are altered through formalin and similar fixating chemicals.
13. Other: Proposed research that addresses a topic not listed above will only be considered if accompanied by a detailed project justification.

Objective 3. Operational research for national public health workforce development and retention

Sustaining public health protection requires a trained workforce to maintain and advance technical capacities. This FOA supports research projects and investigations that identify appropriate models for workforce development, explore alternative incentive and retention strategies where applicable, and collect data regarding gaps in national public health workforce development and training.

Year one applications addressing this objective should include a minimum of one, but not more than three, of the following projects:

1. Assess effectiveness of relevant workforce development models that utilize an alternative cadre, including trained lay persons, to fill workforce gaps in resource-limited settings including for outbreak responses.
2. Develop and evaluate economically feasible alternative incentive and retention strategies and effective training approaches that result in improved workforce performance, sustainability, and incorporation of trained epidemiology staff into Ministries of Health or similar health institutes.
3. Implement and/or develop a centralized database platform to track, monitor and analyze regional workforce development, retention, and distribution data across administrative levels in order to identify specific training needs or resources.
4. Develop and assess costs for accurate, sustainable, and replicable service delivery or training models that can be implemented in-country to improve disease prevention, detection, and response activities.
5. Assess effectiveness of different approaches for building risk communication and behavior change capacity in the public health workforce
6. Assess effectiveness of different approaches for building workforce capacity for translation and dissemination of scientific findings and outbreak response information. Capacity building should include media dissemination, private-public partnerships and scientific writing and policy formulation.
7. Establish and assess new methodologies or models that identify key links, prevention and service delivery approaches across communicable, non-communicable and chronic disease care (including HIV/AIDS and TB) to strengthen the national health care workforce.
8. Identify and assess most effective ways to develop and sustain emergency risk communication staff capacity for preparedness and response.
9. Other: Proposed research that addresses a topic not listed above will only be considered if accompanied by a detailed project justification.

Objective 4. Develop and create an evidence base to establish national public health priorities

Effective public health protection and programmatic resource allocation requires an evidence base to inform country-specific public health priorities and burden of disease rankings. As such, this FOA supports research projects that use surveillance methodologies and modelling to gather data and conduct burden assessments. The results of this research will facilitate the creation of national plans that reflect relevant and specific diseases, the spread of dangerous pathogens, and burden of disease patterns.

Year one applications addressing this objective should include a minimum of one, but not more than three, of the following projects:

1. Develop an evidence base to inform national and regional burden assessments and priority setting processes using surveillance data and or modelling approaches.
2. Identify effective models for conducting national burden of disease assessments of communicable and non-communicable diseases to facilitate effective implementation of a national strategy through population-based methods.
3. Identify effective models for conducting national burden of disease assessments of communicable and non-communicable diseases.
4. Identify and assess cost-effective approaches and methods for collecting data to improve public service

- delivery and provision among displaced or more marginalized populations from remote areas where traveling to larger cities poses a significant challenge.
5. Identify potential high impact public health interventions and conduct cost analysis to determine feasible public health priorities and resource allocations.
 6. Demonstrate effective analysis and utilization of secondary data and, where available, existing surveillance specimen repositories to augment country's surveillance and disease burden assessment capacity.
 7. Other: Proposed research that addresses a topic not listed above will only be considered if accompanied by a detailed project justification.

Target Population

The target population is the general population of countries with either a CDC field office or presence established through deployment.

Collaboration/Partnerships

MoHs remain CDC's primary partners for building and strengthening global public health impact, systems, capacities, and security. CDC continues to work with MoHs, in some cases based on decades-old relationships, to protect and improve public health through a focus on a broad spectrum of activities, including epidemiology and surveillance, laboratory, emergency management, workforce development and training, outbreak response, disease treatment and control, vaccination and eradication, and non-communicable diseases.

Because implementation science can often be strengthened through collaboration with other government ministries and research entities, applicants are encouraged to develop a consortium which should include a government entity such as the Ministry of Health or Agriculture; research institutions from national or international universities and colleges; and/or additional implementing partners, such as a multi-lateral aid agencies or non-government organizations related to program implementation and evaluation, and/or scientific measurement of needs and outcomes for operational research in areas of the application. The applicant should clearly specify how the consortium will strengthen country capacity through their proposed project and should include a letter or letters of support from all consortium members.

Evaluation/Performance Measurement

A plan for ongoing monitoring of study activities should also be included in the application, including investigator monitoring of regulatory compliance, strength of research design, data quality, laboratory quality, and surveys that reflect target population, as applicable to the proposed research. A timeline with measures of study progress should be described in the application. Progress towards those measures will be reported annually and at project closeout.

Translation Plan

The application should include a timeline for completing the report of the main research findings and for developing and implementing a plan that builds country-capacity. Research partners will share findings with local stakeholders to facilitate partnerships and collaboration whenever possible.

Translation plans are expected to include a process for adapting, translating and disseminating project instruments and training materials as a part of the annual report. The plan should be specific to the project(s) objectives and designed to ensure that the research findings have maximum public health impact.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: \$100,000,000

Anticipated Number of Awards: 0

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: \$0 Per Budget Period

Award Floor: \$0 Per Budget Period

Total Project Period Length: 5 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category: Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

2. Foreign Organizations

Foreign Organizations are eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm DUNS by sending an e-mail to ccrhelp@dnb.com, including Company Name, D-U-N-S Number, and Physical Address, and Country. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>.

Foreign components of U.S. Organizations are eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

4. Justification for Less than Maximum Competition

5. Responsiveness

Applications will be deemed non-responsive and will not be processed further under the following conditions:

- If the application is incomplete, meaning required components of the application package are missing. The applicant will be notified that the application did not meet submission requirements.
- Late submissions will be considered non-responsive See Section IV.3 Submission Dates and Time for more information on deadlines.
- If the applicant is participating in a consortium and does not provide a letter of support from the other members listed in the proposal with the application.
- All appendices must have page numbers and be clearly identified in the Table of Contents.
- Each project should be labeled by Objective and Project number as listed in the FOA.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nsfa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <https://www.sam.gov/portal/SAM/#1>.
- [Grants.gov](#)
- [eRA Commons](#)

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and

Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at <https://www.sam.gov/index.html>.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional.

Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from <http://grants.nih.gov/grants/forms.htm>

Additional instructions for submission:

1. Applicant should include Bullets 2-16 as listed in the PHS 398 application instructions above for each of the Objectives for which they choose to apply.
2. If the PHS 398 does not accept more than one attachment, please upload the Project for each Objective in the Appendix section.
3. Each Objective should include a separate budget that should be within the specified budget for that Objective.
4. Label the Objective and Project you are applying for, using language from the FOA.

3. Letter of Intent

Due Date for Letter of Intent: **05/25/2016**

The **MANDATORY** Letter Of Intent (LOI) is due on or before May 25, 2016. The LOI should be submitted on the applying organization’s letterhead and MUST INCLUDE:

1. Name of the organization or applicant SUBMITTING the application
2. Principal Investigator (name and contact information)
3. The research objective(s) that the project will fall under (one, two, three, or four)
4. The title of the project under each objective (if the project fits under one of the projects examples provided in the FOA it must be referred to by name, using language identical to how it appears in the FOA)
5. Applicants **do not** have to list all members of their proposed consortium, if applicable, in the LOI.

The **MANDATORY** LOI should be sent to:

Kyle Jessop, MPA

Public Health Analyst

Division of Global Health Protection, Overseas Business Operations Branch

1600 Clifton Road

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**Preapplication Conference call: Wednesday, May 18, 8:00 a.m. EST. Toll Free:
1-866-692-3158 Participant code: 94344757**

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

- 1. Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
- 2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
- 3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
- 4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY)
- 5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

- 6. Protection of Human Subjects**
- 7. Inclusion of Women and Minorities**
- 8. Targeted/Planned Enrollment Table** (for New Application ONLY)
- 9. Inclusion of Children**

Other Research Plan Sections

- 10. Vertebrate Animals**
- 11. Select Agent Research**
- 12. Multiple PD/PI Leadership Plan.**
- 13. Consortium/Contractual Arrangements**
- 14. Letters of Support**
- 15. Resource Sharing Plan(s)**
- Appendix**

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA**.

All instructions in the SF424 (R&R) Application Guide

(http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Additional clarification of sections of PHS 398 Research Plan component

3. Research Strategy (includes Significance, Innovation and Approach) - limit of 25 pages per Project per Objective.

(a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

(c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 15, below

1. Significance and Impact
2. Key personnel
3. Biosketches
4. Budget and budget justification

6. Protection of Human Subjects - when addressing the human subjects section please address the following four criteria: the risk, the adequacy of protection against risks, the potential benefits of research to subjects and others, and the importance of knowledge gained.

16. Appendix - if there are consent forms, questionnaires, tables, graphs, or publications, they can be included here.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

A maximum of 25 PDF documents are allowed in the appendix.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 25 PDF files with a maximum of 300 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, *the applicant* must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
 - b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **06/28/2016**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http://www.whitehouse.gov/omb/grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

Restrictions, which must be taken into account while writing the budget, are as follows:

- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Reimbursement of pre-award costs is not allowed.
- Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.
- All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.
- Foreign grantees are subject to audit requirements specified in 45 CFR 75. A non-Federal audit is required if, during the grantee's fiscal year, the grantee expended a total of \$300,000.00 or more under one or more HHS awards (as a direct grantee and/or as a sub-grantee). The grantee may have either
 - (1) a financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those case where the grantee receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or
 - (2) An audit that meets the requirements contained in OMB Circular A-133.
- A recipient capability assessment or other pre-award assessment may be required prior to or post award in order to review the applicant’s business management and fiscal capabilities regarding the handling of U.S. Federal funds. A pre-award assessment will be conducted prior to award to any organization that has never received US Federal Funds.
- If research involves human subjects, funds will be restricted until Federal Wide Assurance (FWA) and Institutional Review Board Approvals (IRB) are in place.

- Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.
- Human Subjects Education Requirement documentation is provided.

Funding Preferences

Preference will be given to those applications which:

- Address multiple objectives. If additional funding becomes available, CDC will have the option to fund additional awards per the four research objectives.
- Comply with resource sharing policies.
- Address different focus areas, geographic distribution, priority diseases, vulnerable populations, and research methodologies.
- Utilize and leverage new and innovation technologies.
- Have an impact in CDC Priority countries, projects, or current initiatives, including but not limited to: global health security, Ebola response, Zika response, country-development and capacity building efforts.
- Use a variety of methodological approaches represented in the application.
- Demonstrate a publication history and the potential impact of publication of proposed research projects and studies in one or more subject areas.

12. Other Submission Requirements and Information

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide/submit/apply_11144.html).

Important reminders: All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide. If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/Electronic_Receipt_avoiding_errors.htm or http://grants.nih.gov/grants/Electronic_Receipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (<http://www.cdc.gov/about/organization/mission.htm>), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects If the research involves human subjects but does not involve one of the six categories of research that are exempt under [45 CFR Part 46](#), the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

(<http://www.cdc.gov/grants/additionalrequirements/index.html>).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http://www.cdc.gov/maso/Policy/Policy_women.pdf and <http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1>) and the policy on the Inclusion of Persons Under 21 in Research (<http://www.cdc.gov/maso/Policy/policy496.pdf>).

Vertebrate Animals The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for

Review of the Vertebrate Animal Section
(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: <http://www.phe.gov/s3/dualuse>. Tools and guidance for assessing DURC potential may be found at:

<http://www.phe.gov/s3/dual-use/Pages/companion-guide.aspx>.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plans HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: <http://www.cdc.gov/grants/additionalrequirements/index.html>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.

- Relevance of the proposed project to program priorities.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this funding opportunity announcement

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

- Projects within in each application will be determined to be research or not and only those that are deemed research will be externally peer reviewed. Those that are not deemed to be research will undergo an objective review.
- Each Project (per Objective) will be reviewed and scored individually. This means that if an applicant submits multiple Projects under One objective, each Project will be reviewed independent of others.
- Applications will be ranked by Objective.
- Applications will be funded in order by score and rank determined by the secondary review panel unless funding preferences or other considerations stated in this FOA apply.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-3: Animal Subjects Requirements](#)

[AR-7: Executive Order 12372 Review](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2010](#)

[AR-12: Lobbying Restrictions](#)

[AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities](#)

[AR-14: Accounting System Requirements](#)

[AR-16: Security Clearance Requirement](#)

[AR-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR](#)

[AR-21: Small, Minority, And Women-owned Business](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

[AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”;, October 1, 2009](#)

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Nonresearch](#)

ARs applicable to HIV/AIDS Awards:

[AR-4: HIV/AIDS Confidentiality Provisions](#)

[AR-5: HIV Program Review Panel Requirements](#)

[AR-6: Patient Care](#)

Organization Specific ARs:

[AR-8: Public Health System Reporting Requirements](#)

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:<http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html>.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: <https://www.fsrs.gov/>.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: <http://www.plainlanguage.gov/plLaw/index.cfm>.

Tobacco and Nutrition Policies The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- <http://www.cdc.gov/nccdpHP/dnpao/hwi/toolkits/tobacco/index.htm>
- <http://www.cdc.gov/obesity/strategies/food-serv-guide.html>

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that

recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at <http://www.phe.gov/s3/dualuse>.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Though awardees retain custody of and primary rights to the data and software developed under these awards, those rights are subject to the Government's rights of access consistent with current DHHS, PHS, and CDC regulations and policies, which state that the Government has the right to: (1) obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and (2) authorize others to receive, reproduce, publish, or otherwise use such data.
- Overseeing all management, administrative, and scientific/programmatic aspects of the research including all data, resources, and operations.
- Providing the necessary personnel and supplies to implement components and analyze the results.
- Collaborating with local senior researchers, CDC researchers and community-based organizations, non-government organizations, or similar community liaison for the duration of the project period on

several activities such as the development of data-collection instruments, specimen-collection protocols, and data-management procedures.

- Awardees will obtain IRB approval for all the collaborators and work with CDC scientists to refine protocols to improve the study and other proposal components based on reviewer's comments in the summary statement.
- Awardee will identify, recruit, obtain informed consent form, and enroll an adequate number of study participants, as determined by the study protocols and the program requirements.
- Follow study participants as determined by the study protocols.
- Establish procedures to maintain the rights and confidentiality of all study participants.
- Agree to share data and specimens with CDC scientists, as well as appropriate international partners.
- Awardees will monitor relevant public health systems through routinely and continuously tracking activities that support each research objective.
- Awardees will perform regular (minimum bi-annual) evaluations of data collection and public health systems for each supported objective, to determine whether or not the project meets the requirements outlined in this FOA.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.
- Monitor the cooperative agreement.
- Collaborate with awardee to establish priorities for the development and implementation of the recipient activities, both among and within each of the areas, through regular meetings and communication.
- Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses.
- Provide technical assistance to the recipient by linking them with other national and international agencies that might provide additional technical or material assistance.
- Collaborate with the affiliated institutions in the development and setting of goals, objectives, effective and innovative strategies and methodologies.
- Provide assistance as requested in the development of a research protocol for IRB review by all collaborating institutions that are participating in the research project, including the CDC IRB, if applicable. Obtain and maintain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
- Projects, if directed by CDC staff and involve the collection of information from 10 or more individuals, and are funded by a grant/cooperative agreement, will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.
- Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses. Based on this, CDC will make recommendations aimed at solving problems and at improving the quality of research outputs and outcomes and timeliness of the research activities.
- If appropriate, Epidemic Intelligence Officer(s) and CDC staff will accompany the awardee with field investigation.
- Provide technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the awardee. All such data collections--where CDC staff will be or are approving, directing, conducting, managing, or owning data--must undergo OMB project determinations by CDC and may require OMB PRA clearance prior to the start of the project.
- It is expected that projects under this FOA will leverage, complement, or synergize with existing CDC-funded global health work. While it is not possible to list every potential relationship to ongoing CDC-funded activities, it is conceivable that new projects would relate to CDC's work in emerging infections, surveillance, influenza and pandemic preparedness, field epidemiology training,

International Health Regulations, global health security, risk communication, community engagement, emergency management, laboratory capacity, and non-communicable diseases.

Areas of Joint Responsibility include:

- None; all responsibilities are divided between awardees and CDC staff as described above.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over \$25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000. See the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) for additional information on this reporting requirement.

All reporting must be timely and organized according to the applicant's established research strategy.

Reporting should also include:

- Clear description of potential population reach (potential beneficiaries) for implementation activities assessed in research project.
- A description of research outputs and outcomes that inform public health action, including intervention design, program planning, and policy development, as well as the scaling up of promising operational approaches to cover vulnerable populations.
- Expenditure tracking of implementation activities. Expenditure tracking should be suitable for subsequent economic analyses.
- Mid-year status or progress updates in addition to HHS required, annual reports.
- If the applicant receives funding for more than one objective then applicant must be able to track projects by objective or focus area so that project activity budgets provide designated funds for each objective; with expenditures tracked by objective area.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to

this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000. See the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) for additional information on this reporting requirement.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, is due 90 to 120 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends.
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required 90 days after the end of the project period.

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (<http://grants1.nih.gov/grants/funding/2590/2590.htm>)
<http://grants.nih.gov/grants/funding/2590/2590.htm>: Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include:*

- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:

- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR

due date, indicate the status in your narrative.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

[eRA Commons Help Desk](#) (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)

Telephone 770-488-2700

Email: ogstims@cdc.gov

Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

Rebecca Bunnell

Center for Global Health

Division of Global Health Protection

770-488-2525

rrb7@cdc.gov

Peer Review Contact(s)

Hylan Shoob

Center for Global Health

Office of the Director for Science

404-639-4796

HShoob@cdc.gov

Financial/Grants Management Contact(s)

Dionne Bounds

Office of Grants Services

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Section 301 (a) of the Public Health Service Act (42 U.S.C. 241 (a)) and Section 307 of the Public Health Service Act (42 U.S.C. 242)

AMENDMENT 2 - GH16-007 FAQ (FREQUENTLY ASKED QUESTIONS)

1. When is the application due? Will there be an extension?

The application due date remains June 28, 2016. This date will not be extended.

2. When is the Letter of Intent to apply due? Is it required? What information should be included?

The Letter of Intent (LOI) is due May 25, 2016 by close of business Eastern Standard Time.

The FOA states that the LOI is mandatory, meaning it is required. If your organization does not submit an LOI, your application will be deemed nonresponsive and will not be forwarded for review. However, submitting an LOI does not mean your organization is required to submit an application.

You will not receive a response from CDC regarding your LOI.

The LOI should be on the applying organization's letterhead, and MUST INCLUDE:

Name of the organization or applicant SUBMITTING the application

1. Principal Investigator (name and contact information)
2. The research objective(s) that the project will fall under (one, two, three, or four)
3. The title of the project under each objective (if the project fits under one of the projects examples provided in the FOA it must be referred to by name, using language identical to how it appears in the FOA)
4. Applicants do not have to list all members of their proposed consortium, if applicable, in the LOI.

3. Who is eligible to apply?

The revised version of the funding opportunity, posted on April 28th, has no special or limited eligibility requirements for applicant organizations. Registration requirements for applicant organizations, stated in Section III, subsection 6 of the FOA remain in effect.

It is very important to ensure the applying organization's registration and password is ready to go at least several weeks prior to the application deadline. Registration requirements are stated in Section III Eligibility Information Sections 6 (Required Registrations) and 7 (Universal Identifier Requirements and System for Award Management). The organization must also be registered in eRA Commons and Sam.gov in order to receive an award.

There will be NO EXCEPTIONS to this requirement. We encourage that you submit your application at least one week before the June 28 deadline – earlier if possible - to give yourself time to work out any issues that may arise with the electronic submission system.

4. Can foreign organizations apply?

Yes, as there is no limitation on who can apply, foreign organizations that are registered on grants.gov are eligible applicants.

Please see the definition provided in section III, part 2 of the FOA to determine if your organization is considered a Foreign Institutions. Per the FOA, the designation of a foreign or domestic institution depends on where the institution’s headquarters are located.

5. Does the FOA allow for applications from consortia?

Yes, consortia may apply, but the application must come from – be submitted by -- an individual organization, registered in grants.gov, that represents the previously established consortium. The applicant organization will be considered the “prime recipient.”

The organization applying on behalf of a consortium may also be a part of a different consortium, or may be a sub-recipient or contractor, on a different application in a different country but cannot be the prime applicant for another FOA. However, participating in a collaboration as a sub-recipient or sub-contractor should not be used to bypass the one application limit as noted previously.

6. Please clarify between proposals/priorities/projects in writing.

The terms proposals and priorities were removed from the FOA with this amendment. For purposes of this FOA, a “project” refers to a research activity that addresses topics under an Objective.

7. In each application, how many projects can be included?

Applications may no more than three projects per objective. There are four objectives. In other words, an application could address one, two, three, or all four of the objectives: Surveillance, Laboratory, Workforce, and Public Health Priorities and include up to three projects per Objective.

This means if the applicant applies for the maximum number of projects under each of the four objectives, the application would include twelve projects (four objectives, three projects per objective equals twelve),

8. Should projects be submitted for all topics under a specific research objective?

No. The maximum number of projects allowed under this FOA is three projects per research objective.

Each project must contain all the components listed in the PHS-398. In a standard SF 424 only one research strategy can be uploaded. Applicants submitting multiple projects can attach the additional projects in the appendix section of the SF 424. Each project should be labeled by Objective and Project number. For example, project one (Develop an evidence-based approach to improve current surveillance systems through strengthening civil registration and vital statistics as well as cause of death certification, risk factor surveillance, data analysis and collection) under Objective one (Operational research for national public health surveillance systems) would be labeled Obj 1 Proj 1 if it is uploaded to the appendix.

9. Is the research strategy is limited to 25 pages per project or per objective?

The research strategy is limited to 25 pages per project.

10. How will projects be reviewed?

Each project will be reviewed and evaluated separately.

11. Can an organization submit multiple applications?

Only one application per organization/institution (normally identified by having a unique DUNS number) may be submitted. However, an organization may be a member (but not the submitting applicant) of other

applications.

12. Can one application can cover multiple countries or should it be separate applications?

Multiple countries may be included in one application if all are a part of the same research strategy.

For example, under Objective one (Operational research for national public health surveillance systems), Project one (Develop an evidence-based approach to improve current surveillance systems through strengthening civil registration and vital statistics as well as cause of death certification, risk factor surveillance, data analysis and collection) can include several countries if all are part of the same research strategy. The only limitation is that only three projects may be submitted per objective.

13. Can an application be submitted that covers multiple countries but with different projects in each country?

An application may be submitted that covers multiple countries with different projects in each country. However, if a different project (or projects) is anticipated in each country, the projects must be submitted individually within the application (including separate research plan, research strategy, and budget). Again, the limit is three projects per objective.

14. Where does the coordinated management plan go in the application?

The coordinated management plan should be a one page document describing how the applicant intends to manage submitted projects and should be uploaded as an “other document” in the appendix. The management plan is a separate document and is not part of the research strategy. There should be one coordinated management plan per application. The coordinated management plan should describe the overall management, regardless of the number of objectives and projects the application may contain.

15. What countries ‘maintain a CDC presence, either through a field office or deployment’ or are aligned with the target population outlined in the FOA?

CDC’s countries of current interest Global Health Security Agenda Priority Countries and those effected by Ebola. Specifically these countries are: Bangladesh, Cameroon, Ethiopia, India, Indonesia, Kenya, Pakistan, Tanzania, Uganda, Vietnam, Guinea, Liberia, Sierra Leone, Burkina Faso, Cote d’Ivoire, Mali, Senegal, Nigeria, Togo, Benin, Gambia, Mauritania, Guinea Bissau, DRC, Ghana, Cambodia, Georgia, Haiti, Jordan, Kazakhstan, Laos (LAO PDR), Malaysia, Mozambique, Peru, Rwanda, Thailand, Ukraine, Caribbean Community (CARICOM - which is an organization of 15 Caribbean nations and dependencies). Further information can be found at www.ghsagenda.org.

Global Disease Detection countries are also included as current priority countries: Bangladesh, China, Egypt, Georgia and the South Caucus, Guatemala and Central America, India, Kazakhstan and Central Asia, Kenya, South Africa, and Thailand.

Countries in the Western Hemisphere affected by Zika (including but not limited to Barbados, Columbia, Dominican Republic, Guatemala, Haiti, and Panama) are also included as CDC priority countries along with Angola.

16. Are research projects supported by this FOA limited to GHSA phase 2; GHSA phase 1; Zika affected; or other pre-established priority countries?

No. The FOA includes funding for many different types of projects of importance to CDC. It is not directed solely for GHSA and / or Zika.

17. Where will funding for these projects come from?

There is no pre-determined funding amount for this FOA. CDC programs may use existing funds or new funding should it become available for highly ranked applicants.

Selected proposals will be either awarded funds directly from any available funding or placed on a list with other ‘awarded but unfunded proposals’ to be supported if money becomes available for the relevant research

topic or geographic region within 12 months after approval.

18. As a laboratory researcher, does this FOA allow for projects using live models in mice in vitro. We are in Columbia studying the pathogenesis of Zika and want to know if this FOA will allow for funding for our research. Additionally, a case control study is being conducted in one city in Columbia and researchers want to replicate in other cities – is it possible to submit application under this FOA?

In this question, the applicant would have to determine if their proposed project using live models of mice in vitro could support development and implementation of a plan to build country capacity. Similarly, the applicant conducting a case control study would have to answer the same question - whether their proposed project would aid in development and implementation of a plan to build country capacity.

The purpose of this FOA is to support development and implementation of a plan to build country capacity related to the four objectives. A project can be submitted to this FOA only if it meets this requirement. We recommend that each organization considering applying to this FOA read carefully the types of projects allowed under the FOA.

19. Is IRB approval required as part of my application?

IRB approval is not required to submit an application. However, if your project is funded then CDC would work with you to make sure you adhere to IRB requirements if the project is deemed to be human subjects research.

20. What are the budget minimums and maximums? Is there a minimum or maximum by project or objective? How many projects will be funded?

There is no established ceiling or floor for this FOA. There is no established number of projects to be funded.

21. Are CDC employees eligible to serve as co-investigators and or collaborators?

CDC employees may not participate in during application preparation and submission. However, post award, CDC employees are eligible to serve as co-investigators on funded projects.

- The limitation on CDC participation/assistance in preparing the application applies to all CDC, as it would for any competitive extramural funding announcement. Since this is a competitive application for CDC extramural research funds, CDC staff cannot participate or provide assistance in preparing the application. Questions from the applicant to CDC staff should be referred to the CDC contacts listed in the RFA. *Ad hoc* assistance by CDC staff could result in an unfair advantage being provided to an applicant or the appearance of providing more information to an applicant, and the organization may be disqualified from competition for an award.
- For competitive extramural research, it is not possible to get a commitment from CDC for specific types of in-kind support prior to approval of the study and a decision by CDC to fund the study.
- Collaboration with CDC is developed only after an award is made.

22. Does each project require its own budget and budget justification?

Yes.

23. If our organization proposes more than one country, per project, in the application, do we need to provide separate budget sheets for each country listed in the project?

No. One budget per project; if proposing multiple projects then provide multiple budgets.